

## § 868.5895

(b) *Classification*. Class II (performance standards).

### § 868.5895 Continuous ventilator.

(a) *Identification*. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification*. Class II (performance standards).

### § 868.5905 Noncontinuous ventilator (IPPB).

(a) *Identification*. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.

(b) *Classification*. Class II (performance standards).

### § 868.5915 Manual emergency ventilator.

(a) *Identification*. A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

### § 868.5925 Powered emergency ventilator.

(a) *Identification*. A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

### § 868.5935 External negative pressure ventilator.

(a) *Identification*. An external negative pressure ventilator (e.g., iron lung, cuirass) is a device chamber that is intended to support a patient's ventilation by alternately applying and releasing external negative pressure over the diaphragm and upper trunk of the patient.

## 21 CFR Ch. I (4–1–12 Edition)

(b) *Classification*. Class II (performance standards).

### § 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification*. An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by a patient while providing mechanical ventilation at a preset rate.

(b) *Classification*. Class II (performance standards).

### § 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification*. A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

(b) *Classification*. Class II (performance standards).

### § 868.5975 Ventilator tubing.

(a) *Identification*. Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]

### § 868.5995 Tee drain (water trap).

(a) *Identification*. A tee drain (water trap) is a device intended to trap and drain water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38796, July 25, 2001]